K120198

JUN - 6 2012

510(k) SUMMARY

SAFETY AND EFFECTIVENESS

Submitted By:

Zest Anchors, LLC
2061 Wineridge Place
Escondido, CA 92029

Contact: Annie Wright
Tel: (760) 743-7744 ext 140
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A) Device Trade Name: LOCATOR® Overdenture Implant System
Common Name: Endosseous Implant Screw
Classification Name: Implant, Endosseous, Root-form
Device Class: 21CFR 872.3640, Class II
Product Code: DZE

B) Date prepared: April 30, 2012

C) Predicate Device:

- Ace Surgical Supply Co., Inc., Ace Surgical Secure-Mini™ LOCATOR® Implant System (K092594)

D) Intended Use:

The LOCATOR® Overdenture Implant System is designed to retain overdentures or partial dentures in the mandible or maxilla.

E) Device Description:

The LOCATOR® Overdenture Implant (LODI) System comprises a narrow diameter endosseous dental implant (2.4mm or 2.9mm in diameter and 10, 12, 14, or 16 mm in length) and a screw-retained abutment (2.9mm platform with cuff heights of 2 or 4mm). The collar of the 2.4mm diameter implant is flared to a 2.9mm platform to accommodate the 2.9mm abutment. The implant is made of Ti 6Al-4V ELI conforming to ASTM F136 and the abutment is made of Ti 6Al-4V ELI conforming to ASTM B348.

F) Technological Comparison:

The LOCATOR® Overdenture Implant (LODI) System comprises a narrow diameter endosseous dental implant and a screw-retained abutment. Similar to its predicate, it is designed to retain overdentures or partial dentures in the mandible or maxilla. The implant diameters and lengths are similar to those cleared in K092594 (Ace Surgical Secure-Mini™ LOCATOR® Implant System) and the material (Ti 6Al-4V ELI) as well as surface texturing (Resorbable Blast Media) is identical. The screw-retained abutment is identical in material, cuff height and platform diameter to that cleared in K092594.

G) Nonclinical Testing:

The following mechanical testing in accordance to ISO 14801 was performed on the LOCATOR® Overdenture Implant (LODI) System and its predicate. The subject device was found to be substantially equivalent to the predicate device when tested side-by-side.

- Static Compression Test
- Dynamic Compression (Fatigue) Test

H. Conclusion:

The LOCATOR® Overdenture Implant System is substantially equivalent to the predicate device cleared in K092594 (Ace Surgical Secure-Mini™ LOCATOR® Implant System) based on similar or identical indications for use, technological comparison and overall device functionality.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Annie Wright
Regulatory Affairs Manger
Zest Anchors, LLC
2061 Wineridge Place
Escondido, California 92029

JUN - 6 2012

Re: K120198
Trade/Device Name: LOCATOR Overdenture Implant System
Regulation Number: Endosseous Dental Implant
Regulation Name: 21 CFR 872.3640
Regulatory Class: II
Product Code: DZE
Dated: April 30, 2012
Received: May 1, 2012

Dear Ms. Wright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120198

Indications for Use

510(k) Number (if known): K120198

Device Name: LOCATOR® Overdenture Implant System

Indications for Use:

The LOCATOR® Overdenture Implant System is designed to retain overdentures or partial dentures in the mandible or maxilla.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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